

Pennsylvania Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001334	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 05/15/2023
NAME OF PROVIDER OR SUPPLIER: ALLEGHENY HEALTH NETWORK ENDOSCOPY CENTER, WESTMORELAND		STREET ADDRESS, CITY, STATE, ZIP CODE: 118 NATURE PARK ROAD, SUITE 200 GREENSBURG, PA 15601			
STATE LICENSE NUMBER: 24761501					
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S 0000	INITIAL COMMENT	S 0000			
S 033A	<p>This report is the result of a State licensure survey conducted on May 15, 2023, at Allegheny Health Network Endoscopy, Westmoreland. It was determined the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Ambulatory Care Facilities, Annex A, Title 28, Part IV, Subparts A and F, Chapters 551-573, November 1999.</p>	S 033A			
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE			TITLE:		(X6) DATE:

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S 033A	Continued from page 1 553.3 (1) Governing Body Responsibilities 553.3 Governing Body responsibilities include: (1) Conforming to all applicable Federal, State, and local laws. This REGULATION is not met as evidenced by:	S 033A	Reporting process was reviewed: what qualifies as an incident, serious event, & infrastructure failure, and reporting process to PA-PSRS: Pennsylvania Patient Safety Reporting System. Reporting process and associated policies will be reviewed with all staff on June 15, 2023. Audit goal: to audit 100% of RL6/PSRS reports monthly, goal is 100% for 3 months. After goal is obtained, every RL6 report and PSRS report will be entered according to our present process. Monthly audits of all incident reports will be done to assure events are entered into the PSRS reporting system by the administrator. Administrator will meet monthly with the Patient Safety Nurse to review the prior month's RL6/incident reports and PSRS reports to assure all events are entered appropriately. The audits of incident reporting is in place. Results of these audits are reported during the quarterly Quality meetings, the Med-Exec meetings, and to the Board of Managers. Completion date: July 31, 2023.	Completion Date: 06/08/2023 Status: APPROVED Date: 06/13/2023	

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S 033A	<p>Continued from page 2</p> <p>Based on a review of facility documentation and staff interview (EMP), it was determined that the facility failed to conform to all applicable federal, state, and local laws by failing to report infrastructure failure.</p> <p>"Act 13 of 2002 MEDICAL CARE AVAILABILITY AND REDUCTION OF ERROR (MCARE) ACT"</p> <p>Section 313. Medical facility reports and notifications.</p> <p>(c) Infrastructure failure reports. -A medical facility shall report the occurrence of an infrastructure failure to the department within 24 hours of the medical facility 's confirmation of the occurrence or the discovery of the infrastructure failure. The report to the department shall be in the form and manner prescribed by the department.</p> <p>Definitions from Act 13, Chapter 3. Patient Safety:</p> <p>"Infrastructure failure." An undesirable or unintended</p>	S 033A			

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S 033A	<p>Continued from page 3</p> <p>event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.</p> <p>This is not met as evidenced by:</p> <p>On May 15, 2023, review of facility material, "Allegheny Health Network Westmoreland Endoscopy Center Patient Safety Plan" last reviewed, August 29, 2022, revealed "...Infrastructure Failure: An undesirable or unintended event, occurrence or situation involving the Infrastructure of a medical facility or the discontinuation or significant disruption of a service that could seriously compromise patient safety...Infrastructure Failures shall be reported to the Department of Health within 24 hours of confirmation in the form and manner prescribed by the Department..."</p> <p>On May 15, 2023, review of facility policy, "3M ATP Policy", last dated 1/4/22, revealed "...AHN recognizes its responsibility to provide a safe</p>	S 033A			

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S 033A	Continued from page 4 environment, given the criticality of the manual step to effectively disinfect medical devices...All flexible endoscopes will be tested once weekly using clean trace monitoring system...". On May 15, 2023, review of reports to the Department of Health, revealed no infrastructure failures due to clean trace systems not working or lack of clean trace supplies, resulting in no testing were reported from February 2, 2023, through May 12, 2023. On May 15, 2023, at 2:20pm, interview with EMP1 and EMP2 confirmed that clean trace testing system broke on February 2, 2023, when a work order was placed. After receiving the loaner, it was not able to be used due to unavailability of swabs. Clean trace testing was not done from February 2, 2023, until May 5, 2023. On May 5, 2023, all ten scopes for the facility had clean trace completed and passed. On May 12, 2023, only four scopes were completed for clean trace due to unavailability of swabs. When asked if all ten scopes are currently in use, EMP2 confirmed that they were.	S 033A			

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S 033A	Continued from page 5 On May 16, 2023, at 1:01pm, EMP1 confirmed that this had not been reported as an infrastructure failure.	S 033A			
S 53B0		S 53B0			

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S 53B0	Continued from page 6 555.3 (b) Requirements Privileges granted shall reflect the results of peer review or utilization review programs, or both, specific to ambulatory surgery. This REGULATION is not met as evidenced by:	S 53B0	A revised peer review process will begin on July 1, 2023. This process will include collecting surgeon volumes, chart reviews, complication rates, complications and infections. The information collected will be reviewed by the Credentialing Board for recredentialing. The facility manager will assure the information is sent for credentialing. Over the next 3 months, credentialing will reach into the facility for peer review information. The facility administrator will audit the candidates for credentialing on a monthly basis and any negative data will be reviewed by the Credentialing Board of the ASCs. Results of this process will be communicated during quarterly Quality meetings, Med-Exec committee meetings, and to the Board of Managers. Completion date: July 31. 2023.	Completion Date: 06/08/2023 Status: APPROVED Date: 06/12/2023	

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S 53B0	<p>Continued from page 7</p> <p>Based upon a review of facility documents, credential files (CF), and employee interview (EMP), the facility failed to demonstrate that the clinical privileges granted reflected the results of peer review or utilization review in 10 of 10 credential files.</p> <p>Findings Included:</p> <p>On May 15, 2023, a review of the Allegheny Health Network Surgery Center Medical Staff Bylaws (Last Revised: May 27, 2023) revealed the following:</p> <p>"Article 3- <u>Qualifications, Conditions and Responsibilities: #A.1 Threshold Eligibility Criteria:</u></p> <p>(9) (i) demonstrate recent activity in their primary area of practice, during the last two years..."</p> <p>On May 15, 2023, peer review data was requested for reappointment for 10 of 10 files to verify the findings of clinical competence from the Department Chair for the new appointment term. No data was presented.</p> <p>On May 15, 2023, at 12:15pm, EMP5 stated that the results of peer review/utilization review were contained in a separate file in quality assurance.</p> <p>On May 15, 2023, at 2:00pm, EMP4 reiterated that the results of peer review/utilization review were contained in a separate file and no data was</p>	S 53B0			

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S 53B0	Continued from page 8 presented.	S 53B0			
S 552B	555.22 (b) Surgical Services - Preoperative Care 555.22 Pre-operative Care (b) A written statement indicating informed consent, obtained by the practitioner, and signed by the patient, or responsible person, for the performance of the specific procedures shall be procured and made part of patient's clinical record. It shall contain a statement which evidences the appropriateness of the proposed surgery, as well as any alternative treatments discussed with the patient. It shall also identify any practitioner who shall participate in the surgery. This REGULATION is not met as evidenced by:	S 552B	Audit goal: 30 chart audits/month for 3 month period of time at a goal of 100% will be completed by the Director of Nursing with the AHN Surgery Center Quality Control Chart Audit form. If any discrepancies, they will be reported to the facility administrator, follow up will be conducted and physician/staff reeducated as appropriate. After this time frame, 10 chart audits/month will be completed by the administrator or DON, which is our current process. This process will be provided as education to the staff in a staff meeting on June 15th, 2023. Results of this process will be communicated during quarterly Quality meetings, Med-Exec committee meetings, and to the Board of Managers. Completion date: July 31, 2023.	Completion Date: 06/08/2023 Status: APPROVED Date: 06/13/2023	

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S 552B	Continued from page 9 Based on facility materials, review of medical records (MR), and interview with facility staff (EMP), it was determined that the facility failed to ensure a properly executed informed consent form was completed for one of ten medical records reviewed (MR7). Findings include: On May 15, 2023, review of facility policy "Informed Consent", last dated 11/9/22, revealed "...It is the surgeon's/proceduralist's responsibility to explain to the patient the procedure and risks involved, and it must be documented...". On May 15, 2023, review of MR7, date of service 4/27/23, revealed that the informed consent for the procedure did not include the procedure that would take place. On May 15, 2023, at 11:30am, EMP2 confirmed the above findings.	S 552B			
S 6123		S 6123			

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S 6123	Continued from page 10 561.2 (c) Pharmaceutical Service 561.2 Pharmaceutical Service (c) Contracted pharmaceutical services shall be provided in accordance with the same ethical and professional practices and legal requirements that would be required if these services are provided directly by the organization. This REGULATION is not met as evidenced by:	S 6123	The Pharmacy contract is being reviewed in the Master Services Agreement. A licensed individual (RN/CRNA) will check facility medications and report to the pharmacy on a monthly basis. The policy will be amended to reflect changes. A pharmacist will tour the facility twice per year. The facility administrator will audit the monthly outdates forms and assure a pharmacist comes to the facility twice per year. This process and changes will be provided to all staff in our staff meeting: June 15, 2023. Results of this process will be communicated during quarterly Quality meetings, Med-Exec committee meetings, and to the Board of Managers. Completion date: July 31, 2023.	Completion Date: 06/08/2023 Status: APPROVED Date: 06/12/2023	

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S 6123	Continued from page 11 Based upon a review of facility documents, and staff interview (EMP) it was determined that the facility failed to assure adherence to contracted terms and conditions for management of the pharmacy. Findings Included: On May 15, 2023, a review of the Master Services Agreement between West Penn Allegheny Health System and Allegheny Clinic d/b/a Allegheny Health Network Endoscopy Center (Executed 1st day of April 2023)- Appendix 4, Pharmacy Services revealed the following: "1. Services: AHN shall, through its employed pharmacists and pharmacy technicians ensure that necessary and appropriate storage, controlled substance documentation and drug outdate inspections are carried out at the Surgery Center. Services will be provided in accordance with ethical and professional practice and Federal and State Laws. Specifically, 1. A registered pharmacist or designate will make monthly inspections of all areas within the Surgery Center where pharmaceuticals are stored. These inspections will include reviews of at least the	S 6123			

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S 6123	Continued from page 12 following: All medication storage areas (including crash carts); all anesthesia carts; medication outdates; controlled substance count log sheet validations; refrigerator checks." On May 15, 2023, a review of the pharmacy inspection reports from April 2022 through March 2023 revealed that two of ten inspections were not performed by the technician in a timely manner. In April 2022, the inspection was due for completion on April 30, 2022 and was not performed until May 16, 2022 (16 days late). The pharmacist countersigned the technician's inspection on May 16, 2022. The inspection due on February 28, 2023 was completed on April 11, 2023 (42 days late) by the technician, and countersigned by the pharmacist on May 1, 2023. On May 15, 2023, a review of the pharmacy inspection reports from April 2022 through March 2023 revealed that two of twelve inspections were not completed, July 2022 and August 2022. On May 15, 2023, it was noted that the pharmacy inspection due on April 30, 2023, was not	S 6123			

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S 6123	Continued from page 13 completed. On May 15, 2023, it was noted that 10 of 10 inspections were completed by a pharmacy technician and countersigned by the offsite pharmacist. There was no evidence of the pharmacist being on site during the preceding 12-month period to validate the technician's findings. On May 15, 2023, at 12:52pm, the above findings were validated by EMP1.	S 6123			
S 6403		S 6403			

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S 6403	Continued from page 14 563.12 (2) Form and Content of Record 563.12 Form and content of record The ASF shall maintain a separate medical record for each patient. Each record shall be accurate, legible and promptly completed. Patient medicals shall be constructed to stand alone and be easily identified as ASF records. Medical records must include at least the following: (2) Pertinent medical history and results of physical examination This REGULATION is not met as evidenced by:	S 6403	All CRNAs employed at the center will be reeducated by the Chief CRNA on proper D/C criteria: respiratory discharge parameters in Epic, i.e. Discharged unlabored on room air. Chart audits of CRNA discharge criteria: 3/day for 3 month period of time at 100% will be completed by the Director of Nursing . After this time frame, 10 random audits will be completed by the DON 3 days/month. Results of the audits will be reviewed with the Chief CRNA monthly or as needed. The random audits will be completed to assure the discharge criteria is met. Results of this process will be communicated during quarterly Quality meetings, Med-Exec committee meetings, and to the Board of Managers. Completion date: July 31, 2023.	Completion Date: 06/08/2023 Status: APPROVED Date: 06/13/2023	

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S 6403	Continued from page 15 Based on review of facility materials, review of medical records (MR), and interview with facility staff (EMP), it was determined that the facility failed to ensure that the anesthetist properly evaluated the patients for discharge criteria for five of ten records reviewed (MR1, MR6, MR7, MR8, and MR9). Findings include: On May 15, 2023, review of facility policy "Discharge of Patients from PACU", last dated 11/28/22, revealed "...Patients will be discharged from the PACU by the Anesthesiologist when the discharge criteria is met...After evaluation by an anesthesia provider an order will be written to give permission for discharge upon meeting the discharge criteria outlined below...Patient's airway will be evaluated for all general and sedation cases and ensure there is no obstruction prior to discharge...". On May 15, 2023, review of MR1, date of service, 6/17/2023, revealed at 1254 "Anesthesia Post Procedure Note...Respiratory: Face Mask...Patient does meet PACU D/C Criteria...". On May 15, 2023, review of MR6, date of service,	S 6403			

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NAME OF PROVIDER OR SUPPLIER: ALLEGHENY HEALTH NETWORK ENDOSCOPY CENTER, WESTMORELAND			STREET ADDRESS, CITY, STATE, ZIP CODE: 118 NATURE PARK ROAD, SUITE 200 GREENSBURG, PA 15601		
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S 6403	Continued from page 16 4/24/2023, revealed at 1331 "Anesthesia Post Procedure Note...Respiratory: Face Mask...Patient does meet PACU D/C Criteria...". On May 15, 2023, review of MR7, date of service, 4/27/2023, revealed at 0948 "Anesthesia Post Procedure Note...Respiratory: POM Mask...Patient does meet PACU D/C Criteria...". On May 15, 2023, review of MR8, date of service, 4/28/2023, revealed at 1226 "Anesthesia Post Procedure Note...Respiratory: POM Mask...Patient does meet PACU D/C Criteria...". On May 15, 2023, review of MR9, date of service, 4/28/2023, revealed at 1359 "Anesthesia Post Procedure Note...Respiratory: Face Mask...Patient does meet PACU D/C Criteria...". On May 15, 2023, at 11:30am, EMP2 confirmed the above findings.	S 6403			
S 6701		S 6701			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 39C0001334	(X2) MULTIPLE CONSTRUCTION: A. BLDG: <u>00</u> B. WING: _____		(X3) DATE SURVEY COMPLETED: 05/15/2023
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S 6701	Continued from page 17 567.1 CHAPTER 567 - ENVIRONMENTAL SERVICES 567.1 Principle The ASF shall have a sanitary environment, properly constructed, equipped and maintained to protect surgical patients and ASF personnel from cross-infection and to protect the health and safety of patients. This REGULATION is not met as evidenced by:	S 6701	AHN Periop leaders will meet on June 9, 2023 to discuss 3M ATP testing of endoscopes, this was completed 6/9/2023. Prior discussions with AHN GI leaders, SGNA: Society of Gastroenterology Nurse and Associates, and Olympus, suggest that 3M testing of endoscopes is above and beyond what is required. ATP testing is required of side channeled scopes such as ERCP and EUS scopes. The policy will be presented to peri-op leadership to suggest quarterly testing of scopes and changing from a policy to a guideline: completed 6/9/2023. Discussion with the network Director of Infection Prevention occurred on June 12, she has directed the ASC Leadership to proceed. The guideline will be presented to the facility Infection Prevention Committee on July 15, 2023. Results of ATP testing will be reviewed by the facility administrator and DON, results will be communicated to the VP of the ASCs quarterly. This process and changes will be	Completion Date: 06/08/2023 Status: APPROVED Date: 06/12/2023	

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S 6701	Continued from page 18	S 6701	provided as education to the staff on June 15, 2023. Results of this process will be communicated during quarterly Quality meetings, Med-Exec committee meetings, and to the Board of Managers. Completion date: July 31, 2023.		

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S 6701	Continued from page 19 Based on review of facility documents and interview with facility staff (EMP), it was determined that the facility failed to ensure that the ASF provided a sanitary environment that protected patients from cross-infection to protect the health and safety of patients. Findings include: On May 15, 2023, review of facility policy, "3M ATP Policy", last dated 1/4/22, revealed "...AHN recognizes its responsibility to provide a safe environment, given the criticality of the manual step to effectively disinfect medical devices...All flexible endoscopes will be tested once weekly using clean trace monitoring system...". On May 15, 2023, at 2:20pm, interview with EMP1 and EMP2 confirmed that clean trace testing was not done from February 2, 2023, until May 5, 2023. On May 5, 2023, all ten scopes for the facility had clean trace completed and passed. On May 12, 2023, only four scopes were completed for clean trace. When asked if all ten scopes are currently in use, EMP2 confirmed that they were.	S 6701			

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S 6701	Continued from page 20	S 6701		
S 6747	<p>567.43 Ventilation System</p> <p>The ventilation system shall be inspected and maintained in accordance with the written maintenance schedule to ensure that a properly conditioned air supply meeting minimum filtration, humidity and temperature requirements is provided in critical areas such as the surgical and recovery suites under Chapter 571 (relating to construction standards).</p> <p>This REGULATION is not met as evidenced by:</p>	S 6747	<p>The ASC facility policy related to temperature and humidity will be amended to assure the correct FGI Guideline parameters are referenced for the proper locations in the center. Temperature and humidity readings will be documented daily and follow up completed by facility manager as needed. The facility administrator will review monthly documentation and any deficiencies will be escalated to facilities.</p> <p>This process and changes will be provided to all staff on June 15, 2023. Results of this process will be communicated during quarterly Quality meetings, Med-Exec committee meetings, and to the Board of Managers.</p> <p>Completion date: July 31, 2023.</p>	<p>Completion Date: 06/08/2023 Status: APPROVED Date: 06/12/2023</p>

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S 6747	Continued from page 21 Based on review of facility documents and interview with facility staff (EMP), it was determined that the facility failed to ensure proper temperature requirements were provided in the recovery rooms. Findings include: On May 15, 2023, review of "Guidelines for Design and Construction of Outpatient Facilities" dated 2014, revealed "...Recovery room...Design Temperature 70-75 degrees Fahrenheit...". On May 15, 2023, review of facility policy "Out of Range Temperature in the Operating Room Humidity Control " last dated 5/18/2023, revealed "...Temperature of the Operating Rooms and Preop/PACU shall be maintained at 68 to 75 degrees F...". On May 15, 2023, review of temperature and humidity logs revealed, on 5/9/23 that the rear recovery room was 69.2324 degrees Fahrenheit, on 5/10/23 the recovery room was 69.5906 degrees Fahrenheit, on 5/11/23 the recovery room was 68.7394 degrees Fahrenheit, and on 5/12/23 the recovery room was 69.5458 degrees Fahrenheit.	S 6747			

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S 6747	Continued from page 22 No follow up was documented. On May 15, 2023, at 1:30pm, EMP6 confirmed the above findings.	S 6747			



Certified End Page

ALLEGHENY HEALTH NETWORK ENDOSCOPY CENTER, WESTMORELAND

STATE LICENSE NUMBER: 24761501

SURVEY EXIT DATE: 05/15/2023

**I Certify This Document to be a True and Correct Statement of Deficiencies and
Approved Facility Plan of Correction for the Above-Identified Facility Survey**

A handwritten signature in black ink that reads "Jeane Parisi".

Jeane Parisi
Deputy Secretary for Quality Assurance

A handwritten signature in black ink that reads "Debra L. Bogen MD".

Debra L. Bogen, MD, FAAP
Acting Secretary of Health



THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY